REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-22 are pending in this application. The "comprises of/consists of" language in previous claim 8 and 20 have been separate into the present claims 8, 20, 23 and 24 (also has been corrected in claims 6 and 9). No new matter has been added by this amendment.

Applicants note the finality of the restriction requirement and reserve the right to petition the finality of the decision if the withdrawn claims are not rejoined with the presently examined claims (In summary, the search notes of 7 February 2008 and search strategy of 22 January 2008 do not reflect that expanding the search to the full scope of the invention would have been an undue burden on the Office and as this application is a National Stage application of PCT/EP2004/008346, the present holding of lack of unity of invention is incongruous with the previous holding for this application – see first page of Form PCT/IB/373 attached to this response)

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

Request for removal of 3rd party document from Image File Wrapper

Upon review of the Image File Wrapper (IFW) for this application, in addition to the papers associated with the Office Action which were entered into the IFW on 7 February 2008, there was also a file described as "Claims" which was also entered on this date.

The applicants did not submit this file and the claims in this document appear to be directed to another application (SN: 11/680,727 – "X-Ray Recording Device with an X-Ray Detector and an X-Ray Emitter") which is not owned by the applicants or is being prosecuted by

the applicants' representatives. There was no indication in the Office Action that this was intended to be part of the papers to be mailed to the applicants.

As this paper appears to be unrelated to the present invention and was inadvertently entered by the PTO, the applicants request removal of this file from the IFW for this application.

II. THE OBJECTIONS TO THE CLAIMS HAVE BEEN OVERCOME

The objections to claim 8 is not understood as the claims from the preliminary amendment which was filed on 24 February 2006 show that claim 8 was dependent on claim 6 (not claim 7) which was a claim that was under examination.

III. THE 35 U.S.C. 112, 2nd PARAGRAPH REJECTION HAS BEEN OVERCOME

Claims 8 and 20-22 were rejected for allegedly failing to particularly point out and distinctly claim the subject matter that the applicant regards as their invention. The claims have been amended to address this rejection (see explanation in I. above).

IV. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

Note: As there has been no indication that the restriction/election of species has been withdrawn or that the scope of the examination was expanded beyond the applicants' elected species, the invention was presumed to be examined for the election wherein:

1. The patch is a matrix-type patch
2. The adhesive is a synthetic rubber which in turn is comprised of styrene-butadiene-styrene block copolymer
3. The another penetration enhancer is an N-methyl pyrrolidone
4. The preservative is an organic acid
5. The backing comprises of polyester.

As such, by virtue of the restriction/election of species requirement, this election was deemed to be patentably distinct from other elections which could have been made by the applicants.

1. Claims 1-6 and 11-22 were rejected as allegedly being obvious by Fischer et al. (U.S. Patent 6455066 – "Fischer").). The applicants request reconsideration of this rejection for the following reasons.

In order to establish *prima facie* obviousness, all claim limitations must be taught or suggested by the prior art reference or be within the knowledge of those of ordinary skill in the art. *See MPEP 2143.03.* In addition, for the purposes of this application, any reference which fails to teach any of the elected elements described above, would be considered to be a patentably distinct invention. *See MPEP 806.04(h).* However, Fischer fails to teach or suggest all of the limitations of the applicants transdermal formulations.

First, the applicants' invention is directed toward a ***transdermal*** formulation whereas the invention of Fischer is directed toward an ***intradermal*** composition. The differences in administration is well known in the art and is even addressed by Fischer themselves in the background of their invention (see col. 1, lines 39-48).[1] As one of ordinary skill in the art would recognize that intradermal administration is intended to ***avoid*** any transdermal absorption, the Fischer reference would not be readable upon or suggestive of the applicants' transdermal formulation.

Second, Fischer is directed toward the delivery of an ***anesthetic*** whereas the applicants' transdermal formulation is directed toward delivery of an ***opioid analgesic*** from the phenanthrene group which is consistent with their disclosed methods of delivery, i.e. Fischer wants localized delivery of their anesthetic and to avoid systemic delivery whereas the applicants' invention wants to provide systemic delivery to maximize the pain relief associated with the opioid analgesic.

Moreover, Fischer recognized that the behavior of a penetration enhancer is strongly dependent on the drug (see col. 2, lines 35-41) and as such one of ordinary skill in the art would not impute the penetration activity of aloe vera with an anesthetic as being predictive of the activity with an opioid analgesic and in this instance, it is uncertain what relevance of such

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[1] "In general, drug administration via the skin is divided into two categories: 1) ***transdermal*** administration and 2) ***intradermal*** administration. Transdermal administration involves transport through the skin and into the blood stream to treat systemic diseases. One the other hand, intradermal administration is intended to impart a cutaneous effect, while keeping the pharmocological effects of the drug localized to the intracutaneous regions of drug penetration and deposition. ***Ideally, intradermal absorption occurs with little or no systemic absorption or accumulation.***" (emphasis added)

predictability would be as Fischer and the applicant are directed toward inventions with opposite modes of action.

Third, Fischer also lacks a teaching for some of the elected features of the applicants' claimed invention, i.e. Fischer does not teach a matrix-type patch or that the adhesive is a synthetic rubber which in turn is comprised of styrene-butadiene-styrene block copolymer.

2. Claims 1-6, 8 and 11-22 were rejected as allegedly being obvious by Fischer et al. (U.S. Patent 6455066 – "Fischer") as applied to claims 1-6 and 11-22 above and further in view of Nielsen (U.S. Patent 6171594). The applicants request reconsideration of this rejection for the following reasons.

As claim 8 is ultimately dependent on claim 6, the applicants response above also address the rejection of claim 8.

The applicants further add that Fischer is silent as to the adhesive being comprised of styrene-butadiene-styrene block copolymer. However, while Nielsen refers to an adhesive matrix of styrene-butadiene-styrene copolymer, there is no reason offered from either Fischer or Nielsen for making this combination.

Nielsen is not directed toward intradermal use as in Fischer and even if it had been directed to transdermal use, Fischer's invention actively teaches away from transdermal use. Nielsen uses their adhesive not for dermal administration of an analgesic, but for securing and sealing an ostomy (an operation where an artificial opening is formed) appliance which is unrelated to Fischer or the applicants' invention.

Moreover, there was no reason offered in the respective teachings of Fischer or Nielsen or from the generally available knowledge of those of skill in the art as to why that particular feature of Fischer needed to be modified, i.e. while it can be obvious to try and modify an invention if there are a finite number of solutions, there was no reason for one of ordinary skill in the art, lacking the applicants' claims as a blueprint, to select the use of a specific adhesive, as the necessary element to be modified; one of ordinary skill in the art could have tried any number of Fischer's other elements of their invention for modification (e.g. different active agent, different reservoirs system, etc.) such that rather than a finite number of solutions, there was an infinite number of solution for an as undetermined problem.

Therefore, for any of the above reasons, claim 8 is not obvious over the combination of Fischer and Nielsen.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
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PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference Analgesic	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/EP2004/008346	International filing date *(day/month/year)* 26 July 2004 (26.07.2004)	Priority date *(day/month/year)* 02 September 2003 (02.09.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant NOVOSIS AG		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☒	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 02 March 2006 (02.03.2006)
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